

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

UNITED STATES OF AMERICA, <i>ex rel.</i>)	Civil Action No. 3:17-cv-00166-RBH
JON VITALE,)	
)	
Plaintiff,)	
)	
v.)	MIMEDX GROUP, INC.’S RESPONSE
)	TO RELATOR’S NOTICE OF
MIMEDX GROUP, INC.)	SUPPLEMENTAL AUTHORITY AND
)	SUGGESTIONS IN OPPOSITION TO
Defendant.)	MOTION TO DISMISS
)	
)	

Defendant MiMedx Group, Inc. (“MiMedx”) hereby responds to Relator’s notice of supplemental authority and his additional briefing styled as “suggestions in opposition to motion to dismiss.” Dkt. 73. Relator uses the Fourth Circuit’s recent decision in *United States ex. rel. Grant v. United Airlines, Inc.*, --- F.3d ---, No. 17-2151, 2018 WL 6786134 (4th Cir. Dec. 26, 2018), to reiterate his arguments in opposition to MiMedx’s motion to dismiss (Dkt. 65). Indeed, buried at the end of his submission, Relator acknowledges that the holding in *Grant* “does not alter the relevant standard here.” Dkt. 73 at 5. MiMedx agrees. *Grant*, in which the Fourth Circuit *affirmed* the district court’s dismissal of False Claims Act claims under Rule 9(b), provides no assistance to Relator, who, like the relator in *Grant*, has failed to adequately allege that any false claim was presented to the federal government as a result of MiMedx’s alleged conduct.

The relator in *Grant* alleged that defendant United, a subcontractor to another government subcontractor, certified that repair work on U.S. Air Force aircraft had been completed when it had not. *Grant*, 2018 WL 6786134, at *1. The Fourth Circuit affirmed the

dismissal of the relator's False Claims Act claims under 31 U.S.C. §§ 3729(a)(1)(A) and (B) because the relator's complaint failed "to allege how, or even whether, the bills for these fraudulent services were presented to the government and how or even whether the government paid United for the services." *Id.* at *4. In so doing, the court concluded that "Rule 9(b)'s heightened pleading standard requires that plaintiffs connect the dots, even if unsupported by precise documentation, between the alleged false claims and government payment." *Id.* at *5. Here, as in *Grant*, Relator's Complaint does not connect the dots.

In his "suggestions in opposition," Relator argues that the "crux of MiMedx's patient assistance program (PAP) grant scheme is MiMedx's effort to obtain and fund grants for patients who would not otherwise be able to meet coinsurance obligations under *Medicare Part D*, while manipulating the submission of PAP grant applications to ensure MiMedx's so-called charitable contributions only fund grants that facilitate *Medicare* reimbursement for MiMedx products."

Dkt. 73 at 5 (emphasis added). Yet Relator's Complaint contains no particularized factual allegations that support this assertion. Relator relies primarily on a single PAN grant approval letter attached to the Complaint as Exhibit G, and contends that this constitutes a "specific example of a patient whose Medicare Part D coinsurance payment was paid as a result of the scheme." Dkt. 73 at 2 (emphasis in original). But the approval letter is no such thing. It is not a claim for payment to a federal healthcare program. Rather, the letter shows only that a patient whom Relator contends is a Medicare Part D participant was approved to receive a grant from PAN. It does not show that the patient used that grant to purchase a MiMedx product at all; in fact, the letter states that "[a]ssistance through the Patient Access Network is *not* tied to any . . . treatment . . . that the patient is currently using," and that the "patient has the right to choose any . . . treatment . . . covered by their insurance plan." Dkt. 1-7 (emphasis added). Nor does the

letter show that the patient or her health care provider ever submitted a claim for reimbursement to Medicare (or any payor) as a result of the grant. This letter does not satisfy the requirement, reaffirmed in *Grant*, that a relator allege “with particularity” that a defendant “presented a false or fraudulent claim to the government, resulting in a ‘call upon the government fisc.’” *Grant*, 2018 WL 6786134, at *3 (quoting *U.S. ex rel. Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 786 (4th Cir. 1999)).

Nor can Relator avoid dismissal by pointing to his unsupported “scheme” allegations. Relator argues that “the entire thrust of [MiMedx’s] scheme is to obtain reimbursement by a federal health insurance program,” and therefore the conduct alleged in the Complaint “necessarily resulted in the submission of false claims.” Dkt. 73 at 5 (emphasis in original). Yet the Complaint’s only allegations regarding the submission of claims for reimbursement from Medicare are wholly conclusory. *See, e.g.*, Dkt. 1 ¶ 47 (“This scheme . . . has resulted in the submission of kickback-tainted claims for reimbursement to federal health insurance programs”); *id.* ¶ 175 (“Defendant knowingly and willfully caused these claims to be presented for payment from federal health insurance programs including Medicare”). The Complaint is devoid of any factual allegation—let alone any factual allegation pled with particularity—that establishes that MiMedx engaged in a pattern of conduct that would “‘necessarily have led[] to submission of false claims’ to the government for payment.” *Grant*, 2018 WL 6786134, at *3 (quoting *U.S. ex rel Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 457 (4th Cir. 2013)) (emphasis in original). Where, as here, a plaintiff does no more than “describe a private scheme . . . [and] then allege simply and without any stated reason for his belief that claims . . . must have been submitted . . . to the Government,” a plaintiff fails to satisfy the “stringent pleading standard” of Rule 9(b). *Id.* at *5. As the *Grant* court reinforced, “Rule 9(b)’s particularity

requirement serves a necessary counterbalance to the gravity and ‘quasi-criminal nature’ of FCA liability” and “appl[ies] with special force to FCA claims and the accompanying presentment requirement.” *Id.* (citation omitted).

CONCLUSION

For the foregoing reasons, and those set forth in MiMedx’s motion to dismiss and reply in support thereof, MiMedx’s motion to dismiss should be granted.

Respectfully submitted,

/s/ Matthew R. Hubbell
 Matthew R. Hubbell
 Federal ID# 5484
 E-Mail: matt.hubbell@klgates.com
 Karen E. Spain
 Federal ID# 11982
 E-Mail: karen.spain@klgates.com
 K&L GATES LLP
 134 Meeting Street, Suite 500
 P. O. Box 22092 (29413-2092)
 Charleston, SC 29401
 Telephone: 843.579.5600
 Facsimile: 843.579.5601

Scott D. Stein (*admitted pro hac vice*)
 E-Mail: sstein@sidley.com
 SIDLEY AUSTIN LLP
 One South Dearborn
 Chicago, IL 60603
 Telephone: 312.853.7000
 Facsimile: 312.853.7036

ATTORNEYS FOR DEFENDANT
 MIMEDX GROUP, INC.

January 8, 2019

Charleston, South Carolina